K132013

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

OCT 2 1 2013

Date Prepared	June 28th, 2013
Submitter Name	Mr. Kim Kuan LEE
Official Contact	Mr. Jim Cassi Vice President - Quality Assurance Americas 9001 Spectrum Center Blvd San Diego CA 92123 USA Tel: (858) 836 6081
Device Trade Name	Swift™ Air
Device Common Name/ Classification Name	Vented Nasal Mask; Accessory to Noncontinuous Ventilator (IPPB)
Classification	21 CFR 868.5905, 73 BZD (Class II)
Predicate Devices	Mirage FX (K102746) Swift™ FX (K090244) Ultra Mirage II (K050359)
Description	The Swift™ Air provides an interface such that air flow from a positive pressure source is directed to the patient's nasal nares. The mask is held in place with adjustable headgear that straps the mask to the face. Swift™ Air is as safe as the predicate devices when used under the conditions and purposes intended as indicated in the labelling provided with the product. Swift™ Air is a prescription device supplied non-sterile.
Intended Use	The Swift™ Air channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device. The Swift™ Air is: • to be used by patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed • intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.
Intended Use comparison	*Comparison with predicate Mirage FX (K102746)* The new device and the predicate Mirage FX mask have identical intended uses. Both are intended to be used with Positive Air Pressure therapy equipment and for the same identical patient population.
Technological Characteristics comparison	*Comparison with predicate Swift™ FX (K090244)* The new device and the predicate mask, provide a seal via a silicone interface. The design of both devices incorporate a pillows that seals under the patient's nasal nares. Both masks are offered

in multiple sizes to ensure adequate fit over the extended patient population.

The main differences with the new device are:
(a) It offers two vent options, a traditional multi-hole vent and a new diffused type vent to provide a continuous air leak to flush out and minimize the amount of CO_2 re-breathed by the patient. Like the predicate mask, the incorporation of these exhaust vents does not interfere with the intended performance of the new device.
(b) The number of components and overall weight is reduced.
(c) The headgear includes a rigidizer component.

Both masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1:2004).

Both masks are constructed of molded plastic and silicone components and fabric / nylon headgear that have been subject to biocompatibility safety evaluation in accordance with FDA Guidance #G95-1 and ISO 10993-1. All materials used in the construction of the new mask are deemed as safe as those of the predicate devices.

Materials used in the construction of components that contact the heated humidified gas pathway are classified as permanent "external communicating devices" (with tissue/bone/dentin). The appropriate biological tests conducted and passed for these components, in accordance with FDA guidance #G95-1 were:

- ISO 10993-3 Genotoxicity,
- ISO 10993-5 Cytotoxicity,
- ISO 10993-6 Implantation and
- ISO 10993-10 Sensitization.

The appropriate biological tests conducted and passed for components considered to be in permanent skin contact, in accordance with FDA guidance #G95-1, were:

- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Sensitization and Irritation

In addition, development of the Swift™ Air device complies with ISO 14971:2007, Medical devices - Application of risk management to medical devices.

Both the new mask and the predicate device are designed to operate on the same *Pillows*, *Mirage* or *Swift* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both devices are identical.

Both the new mask and the predicate device can be reused in the home and hospital / institution environment.

Performance Data

Comparison with predicate Ultra Mirage II (K050359)
The CO_2 performance of the new device (both vent types) and the predicate Ultra Mirage II device are substantially equivalent.

Non-clinical testing data

The CO_2 performance of the new device was tested to ensure the mask design provides adequate venting to flush out the expired CO_2. The testing included physical and functional dead-space measurements. The device satisfied all predefined pass/fail criteria and was shown to be substantially equivalent to the predicate Ultra Mirage II (K050359) device as described previously.

Pressure-flow and through impedance bench test results of the new mask were also substantially equivalent to the predicate Swift FX (K090244) device.

Mechanical integrity and performance of the new device was tested to simulated normal use and reasonable abuse scenarios. The device was also tested to demonstrate that it can withstand the effects of storage temperature, humidity and transportation shock & vibration.

Validation of cleaning and reuse was completed to establish that the device can be safely reused by a single patient, or multipatient reuse in the hospital/institutional environment following validated disinfection protocols. After 20 cycles of cleaning/disinfection in accordance with the methods described in the cleaning / disinfection guide, the device has been shown to function as intended. The device satisfied the pass/fail criteria and was shown to be substantial equivalent to the predicate devices.

Clinical Data

Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate substantial equivalence to the predicate devices.

Substantial Equivalence Conclusion

The new Swift™ Air is as safe and as effective as the predicate devices:

- it has the same intended use;
- it has identical technological characteristics to the predicate devices;
- the new device did not raise any new questions of safety or effectiveness;
- it is at least as safe and as effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 21, 2013

ResMed Corporation
Jim Cassi
Vice President, Quality Assurance Americas
9001 Spectrum Center Blvd.
SAN DIEGO, CA 92123

Re: K132013
Trade/Device Name: Swift™ Air
Regulation Number: 21 CFR 868.5905
Regulation Name: Vented Nasal Mask; Accessory to Non-continuous Ventilator
Regulatory Class: Class II
Product Code: BZD
Dated: July 22, 2013
Received: July 23, 2013

Dear Mr. Cassi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

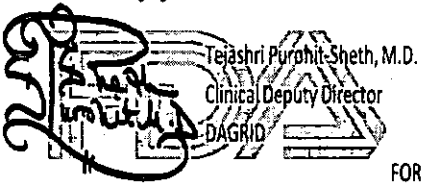
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):
Device Name: **Swift™ Air**
Indication for Use

The Swift™ Air channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device.

The Swift Air is:

- to be used by patients (> 66 lb/30 kg) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

K132013

Anya C. Harry -S
Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=00113155590
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